

REMARKS

Reconsideration of this application is respectfully requested.

I. Status of the Claims

Claim 1 has been amended to incorporate the limitation of claim 3 that the topical composition has a pH of from about 6 to about 8. Claim 3 has been canceled without prejudice. No new matter has been added to the application.

Claims 1 and 4-19 are pending. Because claims 11-13 have been withdrawn from consideration, only claims 1, 4-10, and 14-19 are at issue.

II. Obviousness Rejection

Claims 1, 3-10, and 14-19 have been rejected as obvious over Paul (U.S. Patent No. 6,149,924) in view of Cavazza et al. (EP 0631779 A1), Johnsen et al. (U.S. Patent No. 3,683,939), Vromen (U.S. Patent No. 6,416,769), Yu et al. (U.S. Patent No. 5,589,505), and Deckner et al. (U.S. Patent No. 5,968,528). According to the Examiner, Paul discloses topical compositions comprising L-carnitine and a hydroxy acid, such as glycolic acid, and the secondary references disclose the claimed pH range and the inclusion of various components, such as proteolytic enzymes, skin bleaching agents, and skin lighteners.

In the September 13, 2007 Office Action (page 3), the Examiner argues that Paul “recognize[s] that a pH of 4-6 is desirable for the topical compositions disclosed. See, e.g., col. 16, lines 30-35” The cited passage of Paul relates to the “acidification of skin cells” (*see* col. 16, line 24), and the pH ranges mentioned refer to intracellular pH (col. 16, lines 29-30) and skin pH (col. 16, lines 36-41). Paul does not explicitly refer to the pH of the topical compositions. Furthermore, the “free acids” mentioned by Paul (i.e., isobutyric acid, alpha-methylbutyric acid, and isovaleric acid (*see* col. 16, lines 18-19)) are known to have an offensive odor and therefore would not be desirable for a topical composition.

The presently claimed topical compositions, which have a pH of about 6 to 8, have unexpectedly improved exfoliation performance. *See* page 4, paragraphs [10]-[11], Example 7, and Fig. 1 of the specification. The exfoliating efficacy of topical compositions containing L-carnitine and glycolic acid was tested at pHs ranging from 4.0 to 7.0 using the dansyl chloride method over a period of 20 days. *See* Example 7. A control composition of only a vehicle was also tested. Skin was treated with dansyl chloride (a fluorescent dye), and each composition was applied twice daily to the skin. UV light was used to observe the disappearance of the fluorescence over the 20-day period. When the skin no longer fluoresced, the skin was considered to be completely exfoliated. The results obtained are illustrated in Figure 1 of the specification.

As Figure 1 illustrates, exfoliation by the compositions having pHs of 4.0 and 5.0 was not observed until days 16 and 17, respectively, and showed minor improvement over the control (33% for both compositions at day 17 compared to 11% for the control). In both cases, exfoliation was not complete until day 19 (compared to day 20 for the control).

On the other hand, exfoliation by the compositions having pHs of 6.0 and 7.0 was observed at days 13 and 14, respectively. By day 17, when exfoliation only began to be observed in the more acidic compositions, exfoliation was complete in the compositions having pHs of 6.0 and 7.0. Thus, the compositions having pHs of 6.0 and 7.0 demonstrated superior exfoliating performance over the more acidic compositions.

Paul, Cavazza, Johnsen, Vromen, Yu, and Deckner fail to teach or suggest that a correlation exists between pH and exfoliation performance. Specifically, the references collectively do not disclose or suggest that for compositions containing (a) L-carnitine, acyl L-carnitine, or a salt thereof and (b) a hydroxy acid, proteolytic enzyme, skin lightening agent, or a mixture thereof, a pH of 6-8 yields improved exfoliating properties. Thus, the skilled artisan would not have expected that adjusting the pH as claimed would produce the significantly improved exfoliation observed.

For at least the above reasons, claims 1, 4-10, and 14-19 are not obvious over the cited references. Applicants respectfully request that the rejection be withdrawn.

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance. If there are any remaining issues that the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is kindly requested to contact the undersigned at the telephone number indicated below.

Dated: March 13, 2008

Respectfully submitted,

By /Jay P. Lessler/

Jay P. Lessler

Registration No.: 41,151

DARBY & DARBY P.C.

P.O. Box 770

Church Street Station

New York, New York 10008-0770

(212) 527-7700

(212) 527-7701 (Fax)

Attorneys/Agents For Applicant